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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,170	02/04/2002	Darrel Drinan	05693.0004.NPUS00	8076

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EXAMINER

RADEMACHER, MARK A

ART UNIT PAPER NUMBER

3761

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,170

Applicant(s)

DRINAN ET AL.

Examiner

Mark Rademacher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 1-27, 38-50 and 51-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 28-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the election of species requirement in Paper No. 9 is acknowledged.
2. The applicant has elected the species disclosed in FIGS 7-10. The applicant asserts that claims 51-61 are directed to the embodiment described therein. Claims 51-61 recited a method of delivery including the steps of providing a positive pressure means and providing a negative pressure means, which is not disclosed in conjunction with the elected species. Accordingly, the applicant has listed claims 51-61 in error and these claims have been withdrawn by the examiner.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

4. The information disclosure statement filed on September 3, 2003 (paper no. 4) fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

5. The disclosure is objected to because of the following informalities: It is the examiner's position that applicant has evoked sixth paragraph, means-plus-function language to define applicant's invention. Therefore the examiner requires the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000))
6. Appropriate correction is required.

Claim Objections

7. Claims 28-37 are objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.
8. Specifically, in part (a)(ii) of claim 28, the applicant recites "means for delivering said agent to a device tip assembly". However, in part (b), the applicant recites "a device tip assembly for dispensing said agent". The examiner makes the assumption that the applicant is

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referring to the same device tip rather than to two distinct device tips. The applicant should correct the language of the claim to make clear the same device tip is being recited in part (a) and part (b) by amending the language in part (b) to refer to “the device tip assembly”.

9. Also part (b), the applicant recites “the agent delivery assembly”, which appears to refer to “the agent delivery and aspirating assembly”. The applicant should make an appropriate clarifying correction to the claim.

10. In part (a)(iv) the applicant recites “a means for sealably connecting said agent delivery and aspirating assembly to the device tip assembly”, and in part (b)(iii) recites “a means for sealably connecting the device tip assembly to said agent delivery and aspirating assembly”. These clauses appear to be defining the same feature. The applicant should correct the claim language to make it clear that these clauses are referring to the same structure(s).

11. In claim 54, the applicant recites “wherein said mechanical means is a pump”. However, the applicant has not recited mechanical means in claim 54, or its parent claim 51. It appears that the applicant should have recited “wherein said positive pressure means for delivery of said agent to the orifice is a pump”. As currently recited it is unclear what as “mechanical means” is being referred to in claim 54.

12. The applicant is invited to review the claims for similar lapses in clarity and make corrections where appropriate.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 28-33 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent no. 3398743 to *Shalit*.

15. It appears that the applicant has employed means-plus-function language to define many of the features of the invention. The structures associated with those features recited in means-plus-function language are defined by the applicant's specification. The applicant has asserted that claims 28-37 are directed to the embodiments depicted in FIGS 7-10 and the structure disclosed therewith. Accordingly, the structures and equivalents disclosed in the prior art have been analyzed in that context.

16. *Shalit* discloses a closed system for irrigating that is capable of irrigating a nose or the like. The device includes an agent delivery and aspirating assembly including means for generating positive and negative pressure in the form of hand bulb (10), means for delivering the agent to a device tip assembly in the form of tube (48) and check valves (36) and (52), means for applying negative pressure to the orifice through the device tip assembly in the form of inlet tube (34) and a means for sealably connecting the agent delivery and aspirating assembly to the device tip assembly in the form plastic tube (24).

17. The device tip assembly includes a nozzle means (26), a means for transporting the orifice contents to a storage means in the form of chamber (16) and tube (58) and the means for sealably connecting in the form of tube (34).

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18. *Shalit* discloses use of an irrigating fluid, i.e., a solution. Column 3, line 62. The irrigating fluid and therefore the agent is inherently contained in the orifice contents that sucked out of the orifice.

19. The amount of positive and negative pressure generated can be adjusted by modulating the amount the bulb (10) is squeezed. Moreover, due to their geometry the check valves act as means for controlling the level of positive and negative pressure. The check valves and bulb (10) also act to delay the time between delivery and aspiration as the bulbs.

20. The *Shalit* device includes at least two means for delivering a metered amount of agent to the orifice. First, the bulb (10) is a means for delivering a metered amount of agent to the orifice according to the amount the bulb is depressed. Second, the spring lock or clamp (68) meters the amount of irrigating fluid that enters the bulb (10) and therefore the amount of agent delivered to the orifice.

21. Claims 28 and 34

22. Claims 28 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by *Watson*.

23. *Watson* discloses a medical pump for debris collection that includes an agent delivery and aspirating assembly including means for generating a positive pressure, i.e., bulb (28), means for delivering the agent a device tip assembly, i.e., valve member (22) and flushing path (24), means for applying negative pressure to the orifice through the device tip assembly, i.e., valve member (22) and apertures (16) and means for sealably connecting the delivery and aspirating assembly to the device tip assembly, i.e., circumferential step (4) of the barrel (2).

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24. *Watson* discloses a device tip assembly in the form of a barrel (2) that includes a nozzle element (30) and a means for transporting the orifice contents from the device tip to a storage means in the form of effluent path (26), which flows into and through a storage means defined by the filter (18) and the central tube (20). The storage means is located within the barrel (2).

Additional Pertinent Prior Art

25. The following prior art made considered pertinent to applicant's disclosure.

US patent nos. 1526313 to *Blakeslee*, 2612894 to *Akins*, 1856811 to *Inaki*, 3502078 to *Hill et al*, 869262 to *Pynchon*, 1022601 to *Rumberg et al*, and 1469764 to *Crisenbery*.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Rademacher whose telephone number is (703) 305-0842.

The examiner can normally be reached on Monday through Friday, 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dawson Glenn can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MAR

May 14, 2003

A handwritten signature in black ink, appearing to be 'MAR' with a stylized flourish.A handwritten signature in black ink, appearing to be 'Gul'.

GLENN K. DAWSON
PRIMARY EXAMINER